(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

B9

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 August 2002 (15.08.2002)

PCT

(10) International Publication Number
WO 02/062228 A1

(51) International Patent Classification[7]: A61B 10/00

(21) International Application Number: PCT/US02/02987

(22) International Filing Date: 1 February 2002 (01.02.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/266,806 5 February 2001 (05.02.2001) US

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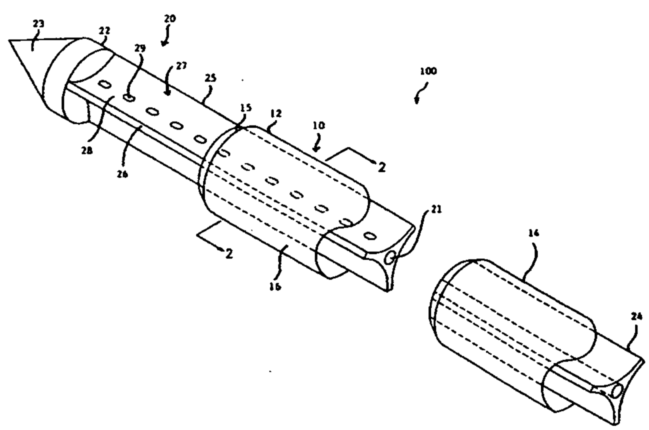
(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: BIOPSY APPARATUS AND METHOD



(57) Abstract: A biopsy apparatus for taking internal tissue samples including an outer knife tube and a trocar rod that includes at least one tissue basket and a piercing tip. The tissue baskets are radially aligned about the longitudinal axis near the distal end. The needle tip is positioned at the distal end of the trocar rod and pierces the tissue of the patient. The outer knife tube includes a distal cutting edge and the trocar rod contains a knife for penetrating a patient's outer tissue. The at least one tissue basket is in fluid communication with a vacuum source through the at least one vacuum passageway in the trocar rod. A method is included wherein the outer knife tube and trocar rod penetrate the patient and are positioned within the tissue to be sampled. The knife tube is withdrawn at least partially exposing the at least one tissue basket of the trocar rod. A vacuum is applied and the trocar rod held substantially stationary while the knife tube is repositioned distally to sever the at least one tissue sample. Additional samples can be taken by applying a vacuum to a different tissue basket or repositioning the trocar rod within the knife tube to a new radial orientation or position along the longitudinal axis. The at least one tissue samples are withdrawn through the knife tube with the trocar rod.

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BIOPSY APPARATUS AND METHOD

BACKGROUND

1. Technical Field

The present disclosure relates to instruments and methods used for obtaining tissue samples. More particularly, the present disclosure relates to minimally invasive biopsy instruments and methods for obtaining tissue samples.

2. Background of Related Art

It is often necessary to sample tissue in order to diagnose and treat patients suspected of having cancerous tumors, pre-malignant conditions and other diseases or disorders. Typically, in the case of suspected cancerous tissue, when the physician establishes by means of procedures such as palpation, x-ray or ultrasound imaging that suspicious conditions exist, a biopsy is performed to determine whether the cells are cancerous. Biopsy may be done by an open or percutaneous technique. Open biopsy removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy). Percutaneous biopsy on the other hand is usually done with a needle-like instrument and may be either a fine needle aspiration (FNA) or a core biopsy. In core biopsy, as the term suggests, a core or fragment tissue is obtained for histologic examination which may be done via frozen section or paraffin section.

The type of biopsy utilized depends in large part on the circumstances present with respect to the patient and no single procedure is ideal for all cases. Core biopsy, however, is extremely useful in a number of conditions and is being used more frequently.

Intact tissue from the organ or lesion is preferred by medical personnel in order to arrive at a definitive diagnosis regarding the patient's condition. In most cases only part of the organ or lesion need be sampled. The portions of tissue extracted must be indicative of the organ or lesion as a whole. In the past, to obtain adequate tissue from organs or lesions within the body, surgery was performed so as to reliably locate, identify and remove the

tissue. With present technology, medical imaging equipment such as stereotactic x-ray, fluoroscopy, computer tomography, ultrasound, nuclear medicine and magnetic resonance imaging, may be used. These technologies make it possible to identify small abnormalities even deep within the body. However, definitive tissue characterization still requires obtaining adequate tissue samples to characterize the histology of the organ or lesion.

The introduction of stereotactic guided percutaneous breast biopsies offered alternatives to open surgical breast biopsy. With time, these guidance systems have become more accurate and easier to use. Biopsy guns were introduced for use in conjunction with these guidance systems. Accurate placement of the biopsy guns was important to obtain useful biopsy information because only one small core could be obtained per insertion at any one location. To sample the lesion thoroughly, many separate insertions of the instrument had to be made.

Biopsy procedures may benefit from larger tissue samples being taken, for example, tissue samples as large as 10 mm across. Many of the prior art devices required multiple punctures into the breast or organ in order to obtain the necessary samples. This practice is both tedious and time consuming.

One further solution to obtain a larger tissue sample is to utilize a device capable of taking multiple tissue samples with a single insertion of an instrument. Generally, such biopsy instruments extract a sample of tissue from a tissue mass by either drawing a tissue sample into a hollow needle via an external vacuum source or by severing and containing a tissue sample within a notch formed on a stylet. Such devices generally contemplate advancing a hollow needle into a tissue mass and applying a vacuum force to draw a sample into the needle and hold the same therein while the tissue is extracted.

A continuing need exists for percutaneous biopsy apparatus and methods which can reliably extract adequate biopsy sample(s) with a single insertion of the biopsy instrument.

SUMMARY

A biopsy apparatus is provided that employs an outer hollow knife tube with a distal end cutter and a trocar rod removably positioned within the knife tube. The trocar rod includes a piercing tip and at least one tissue basket near the distal end. The at least one tissue basket contains a plurality of through holes that are in fluid communication with at least one vacuum passageway positioned in the trocar rod and a vacuum source.

A biopsy method is provided wherein a biopsy apparatus employing an outer hollow knife tube with a distal end cutter and an inner trocar rod with a piercing tip and at least one tissue basket, penetrates a patient's tissue and is at least partially positioned within the tissue to be sampled. The hollow tube is withdrawn proximally while the trocar rod is held in position to at least partially expose the at least one tissue port to the tissue to be sampled. A vacuum is applied to assist the natural prolapse of tissue into the at least one tissue port and the trocar rod is held in a substantially fixed position while the hollow knife tube is repositioned and the distal end cutter severs a tissue sample. The trocar rod transports the at least one tissue sample through the hollow knife tube.

The invention, together with attendant advantages, will be best understood by reference to the following detailed description of the invention when used in conjunction with the figures below.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the presently disclosed biopsy apparatus are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of one embodiment of the knife tube and trocar rod biopsy apparatus constructed in accordance with the present disclosure;

FIG. 2 is an axial cross sectional view of the biopsy apparatus of FIG. 1 taken along section line 2-2;

FIG. 3 is an axial cross sectional view of a second embodiment of the knife tube and trocar rod biopsy apparatus with a vacuum tube and tissue basket through hole configuration that selectively controls the application of the vacuum to the tissue baskets constructed in accordance with the present disclosure; and

FIG. 4 is an axial cross section view of a third embodiment of the knife tube and trocar rod biopsy apparatus with at least two vacuum passageways constructed in accordance with the present disclosure.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now in specific detail to the drawings in which like referenced numerals identify similar or identical elements throughout the several views, and initially to FIG. 1, the preferred configuration of the knife tube and trocar rod biopsy apparatus 100 (hereinafter referred to as "biopsy apparatus 100") includes a knife tube 10 and a trocar rod 20.

Knife tube 10 includes a distal end 12 and a proximal end 14 wherein tubular wall 16, distal end 12 and proximal end 14 define a lumen concentric to the axis "X." Distal end 12 contains a cutting edge 15.

Trocar rod 20 includes a distal end 22 with an integrated piercing tip or knife blade tip 23 and a proximal end 24. Distal end 22 and proximal end 24 define a longitudinal axis "X" that is concentric with that of knife tube 10. Trocar rod 20 is sealingly engaged and removably positioned within knife tube 10.

For purposes of clarity, only the details of the working distal ends 12 and 22 are illustrated in detail. The proximal ends 14 and 24 may be attached to a suitable handle or actuator to facilitate operation of biopsy apparatus 100 or any of the other biopsy apparatus embodiments or configuration disclosed herein. For example, biopsy apparatus 100 may include a housing wherein knife tube 10 and trocar rod 20 are housed. The housing may include suitable known driving and actuating mechanisms. In one embodiment a penetrating member such as the knife tube and trocar rod may be rapidly movable into position at the target tissue location by a suitable drive mechanism, such as, for example, potential energy devices, drive motors, pneumatic devices, or any other suitable drive mechanism.

Cutting edge 15 has the function of piercing the outer tissue of the patient and severing tissue samples in combination with trocar rod 20. Knife tube 10 is preferably fabricated from a stainless steel, but it could be made of medical grade plastic or composite

molded to contain an integral metal cutting edge 15. Cutting edge 15 is preferably fabricated of stainless steel.

Trocar rod tube 20 wall segments 26 slidingly engage knife tube 10 and define at least one tissue port near distal end 22. As shown in this embodiment, three walls segments 26 define three tissue ports 25, but the quantity, dimensions, location, and configuration of tissue ports 25 is dependent upon the particular application of the knife tube and trocar rod biopsy apparatus 100. Each tissue port 25 contains a concave interior wall 28 that defines a tissue basket 27 and a plurality of vacuum through holes 29. Interior walls 28 also define a vacuum passageway 21 that is in fluid communication with a vacuum source (not shown) and through holes 29. Trocar rod 20 is fabricated as a solid rod injection molded of a polycarbonate, similarly suitable composite materials, or medical grade metals. Knife blade tip 23 is preferably fabricated from stainless steel by a suitable process, such as stamping or metal injection molding.

Referring now to FIG. 2, biopsy apparatus 100 is shown along cross section 2-2 in FIG. 1 with trocar rod 20 positioned concentrically within knife tube 10. Wall 26 slidingly engages the interior circumference of knife tubular wall 16. Interior walls 28 define tissue basket 27, through holes 29, and passageway 21.

In FIG. 3, alternative configuration biopsy apparatus 200 is shown with a trocar rod 220 positioned within a knife tube 210. At least one wall segment 226 slidingly engages an interior circumference of tubular wall 216. Walls 228 define at least one tissue basket 227, a plurality of through holes 229, and a passageway 221 that is aligned with the longitudinal axis "X". A vacuum tube 230 is removably positioned within and sealingly engaged with vacuum passageway 221. Vacuum tube 230 includes a tubular wall 236 that defines a plurality of radially and longitudinally aligned through holes 239 that are in fluid communication with tissue basket 227 and a vacuum source (not shown).

In this configuration, the interior walls 228 define a plurality of longitudinally aligned through holes 229. The length of the preset interval between through holes 229 of tissue baskets 227 are equidistant along the longitudinal axis, but through holes 229 of each tissue basket 227 have a distinct and separate radial alignment.

In operation when in a first position, for example, with vacuum tube 230 positioned

to its distal limit within trocar rod 220, through holes 239 and through holes 229 of a first tissue basket 227 positioned relatively at a "12:00 o'clock" position and are in fluid communication with vacuum tube 230 and those of a second tissue basket relatively positioned at "4:00 o'clock" and a third tissue basket relatively positioned at an "8:00 o'clock" position are blocked from being in fluid communication as a result of the misalignments of their respective through holes 229, 239. By either withdrawing vacuum tube 230 proximally, rotating and repositioning vacuum tube 230 or by solely rotating vacuum tube 230 to a second radial position, aligns and places in fluid communication through holes 239 of vacuum tube 230 with through holes 229 of second tissue basket 227 at the "4:00 o'clock" position. Correspondingly, through holes 229 of first tissue basket 227 at the "12:00 o'clock" position and through holes 229 of third tissue basket 227 at the "8:00 o'clock" position are now misaligned and not in fluid communication. A similar process is repeated to align the through holes 239 of vacuum tube 230 with through holes 229 of third tissue basket 227 at the "8:00 o'clock" position.

Thus, vacuum tube 230 provides the function of selectively directing the orientation of the vacuum to a single tissue basket, depending on its preset position within trocar rod 220, in order to optimize the application of the instrument to a variety of operational scenarios. Further alternative configurations could include radially aligning through holes 239 and 229 to establish fluid communication with at least two tissue baskets simultaneously, for example. This configuration could also include an increased number of radially positioned tissue baskets.

Referring now to FIG. 4 and an additional alternative configuration, biopsy apparatus 300 is shown with a trocar rod 320 positioned within a knife tube 310. Trocar rod 320 includes a wall segment 326 that slidingly engages the interior circumference of tubular wall 316. Interior walls 328 define at least one tissue basket 327, a plurality of through holes 329, and a primary vacuum passageway 321. Primary vacuum passageway 321 contains at least one member 322 that divides primary vacuum passageway 321 into at least one additional secondary passageway 323. The quantity and orientation of secondary passageways 323 corresponds to the quantity and radial orientation of the at least one tissue basket 327 positioned in trocar rod 320. Member 322 could form separate tubular

secondary passageways 323, for example, or any other suitable geometric shape of secondary passageway 323. Passageways 323 provide the function of selectively controlling the application of the vacuum to the at least one tissue basket that has a preferred orientation for the tissue to be sampled. The vacuum applied to each secondary passageway 323 could be from separate vacuum sources, for example, or from a single vacuum source with a switch system for selecting at least one secondary vacuum passageway 323 that corresponds to the desired tissue basket and tissue sampling location.

Biopsy apparatus 100 or any of the other biopsy apparatus embodiments or configurations disclosed herein may be inserted by suitable known techniques, for example, by motor driven or spring fired mechanisms. Alternatively, biopsy apparatus 100 may be inserted manually. In either arrangement, biopsy apparatus 100 or any of the other biopsy apparatus embodiments or configuration disclosed herein may be configured as a hand held apparatus or as part of a frame mounted device. An example of such a device is an image guided positioning apparatus such as a stereotactic imaging machine. Any suitable imaging modality may be used to guide biopsy apparatus to the target tissue.

Referring now to FIGS. 1 and 2, biopsy apparatus 100 in operation pierces the tissue of a patient in a first position wherein trocar rod 20 is concentrically positioned and sealingly engaged within knife tube 10. Biopsy apparatus 100 is then at least partially positioned within a tissue portion. In this configuration, using three tissue baskets 27, trocar rod can be rotatingly positioned within knife tube 10 or have a fixed orientation that is controlled from proximal end 24 wherein a first tissue basket is relatively aligned at a "12:00 o'clock" position, a second tissue basket is relatively aligned at a "4:00 o'clock" position, and a third tissue basket is relatively aligned at an "8:00 o'clock" position.

Once at least partially positioned within a portion of tissue to be sampled, knife tube 10 is withdrawn proximally to at least partially expose tissue basket 27. The prolapse of tissue portion into tissue port 25 is augmented by the application of the vacuum communicated from the vacuum source through passageway 21 to holes 29 defined in the wall 26 of tissue basket 27. Knife tube 10 is then repositioned by translating or using a combined movement rotating and translating edge 15 over tissue basket 27 to sever at least one tissue sample. In the alternative, once knife tube 10 is withdrawn proximally it is then

held substantially in the same position while trocar rod 20 is withdrawn proximally to sever at least one tissue sample against cutting edge 15. The at least one severed tissue sample is retained within the respective at least one tissue basket 27. Trocar rod 20 is then withdrawn proximally through knife tube 10. Additional tissue samples are obtained by radially repositioning the at least one tissue basket 27 within knife tube 10 or repositioning knife tube 10 and trocar rod 20 simultaneously radially or longitudinally. Tissue samples obtained from trocar rod 20, when employed with a fixed angular orientation, are segregated to reduce contamination and as a result of their controlled directional orientation, have the advantage that the samples may indicate a direction of malignancy.

Although the illustrative embodiments of the present disclosure have been described herein with reference to the accompanying drawings, it is to be understood that the disclosure is not limited to those precise embodiments, and that various other changes and modifications may be affected therein by one skilled in the art without departing from the scope or spirit of the disclosure. All such changes and modifications are intended to be included within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A biopsy apparatus comprising:

a knife tube having a distal end cutting edge;

a trocar rod removably positioned in the knife tube, the trocar rod having a distal end with a piercing tip and at least one tissue port defined by an interior wall thereof; and

a vacuum source in fluid communication with at least one vacuum passageway defined by the interior wall of the trocar rod, the at least one vacuum passageway being in fluid communication with the at least one tissue port via a plurality of through holes formed in the interior wall of the trocar rod.

2. A biopsy apparatus according to claim 1, wherein the interior wall of the trocar rod extends to an inner surface of the knife tube.

3. A biopsy apparatus according to claim 1, wherein the at least one vacuum passageway includes a vacuum hub rotatably positioned therein, the vacuum hub being configured and adapted to selectively place at least a selected one of the plurality of tissue ports in fluid communication with the vacuum source.

4. A biopsy apparatus according to claim 3, wherein the at least one vacuum passageway includes a vacuum hub rotatably positioned therein, the vacuum hub being configured and adapted to selectively place at least a selected one of the plurality of tissue ports in fluid communication with the vacuum source.

5. A biopsy apparatus according to claim 4, wherein the vacuum hub comprises a hollow sleeve having at least one opening formed radially therethrough, and wherein the vacuum hub is rotated within the vacuum passageway to radially align the at least one opening of the vacuum hub with the plurality of through holes of a selected one of the plurality of tissue ports.

6. A biopsy apparatus according to claim 3, wherein the vacuum hub comprises a body portion having at least one lumen extending longitudinally therethrough, wherein each lumen is in fluid communication with a respective tissue port via a respective plurality of through holes.

7. A method of obtaining a tissue sample from a patient with a biopsy apparatus comprising the steps of:

positioning a biopsy apparatus in the patient at least partially within a portion of tissue to be sampled in a first position, wherein the biopsy apparatus includes a trocar rod positioned within an outer hollow knife tube covering at least one tissue port of the trocar rod;

repositioning the knife tube to at least partially expose the at least one tissue port of the trocar rod and applying a vacuum to the at least one tissue port;

repositioning the hollow knife tube to sever at least one tissue sample; and

withdrawing the at least one tissue sample in at least one tissue basket of the trocar rod through the hollow knife.

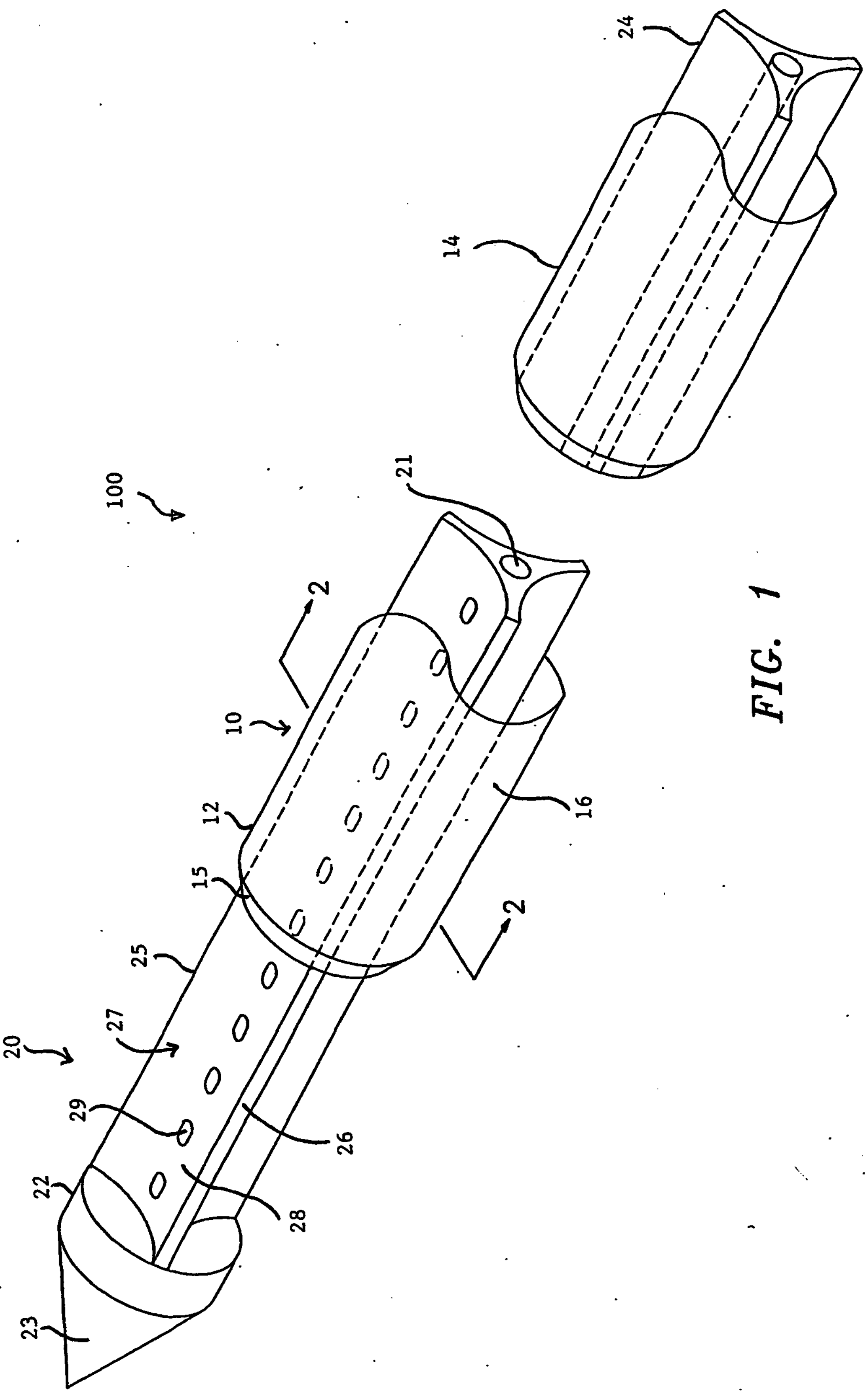

FIG. 1

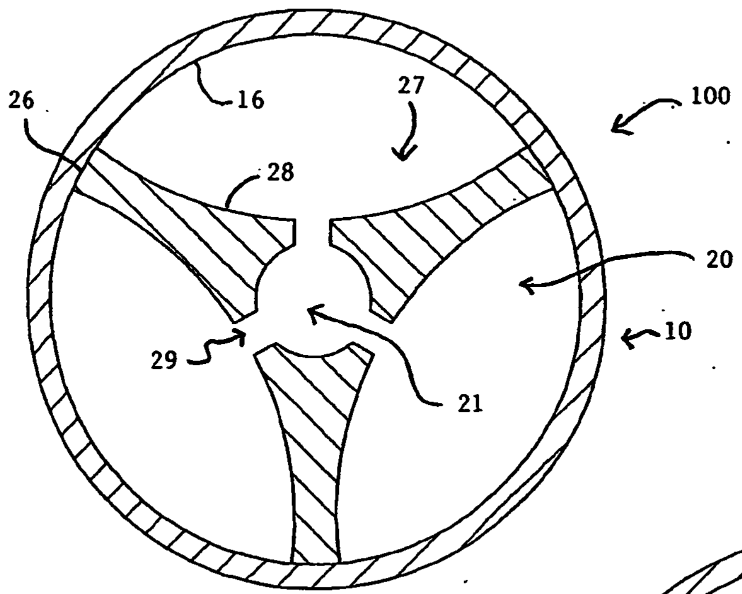

FIG. 2

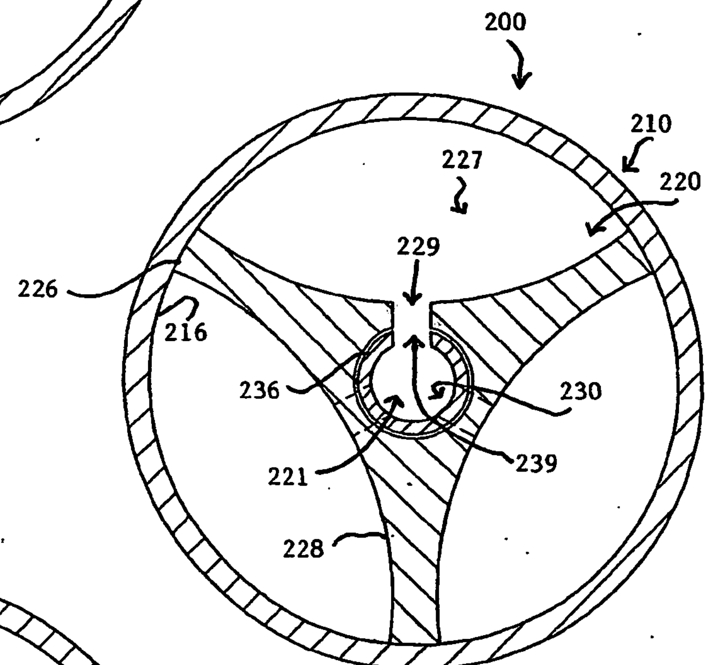

FIG. 3

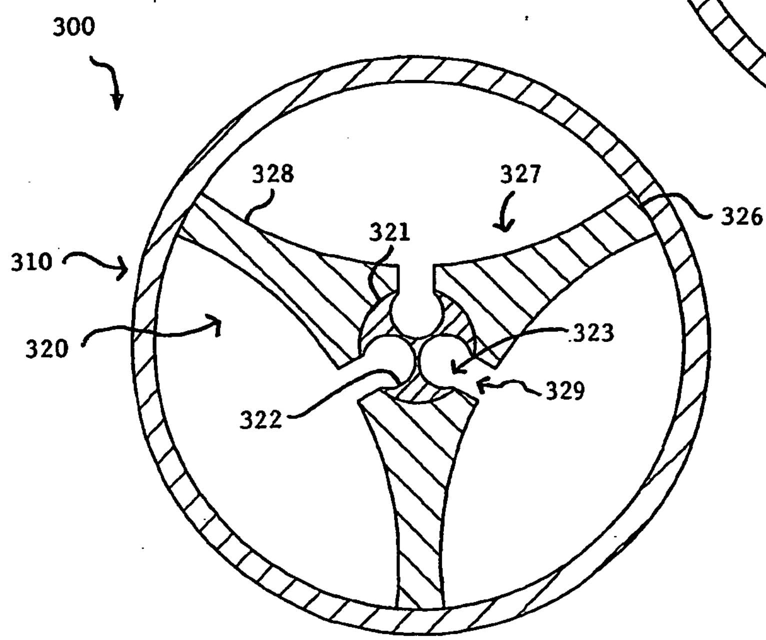

FIG. 4

International Application No
PCT/US 02/02987

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 0 919 192 A (ETHICON ENDO SURGERY INC) 2 June 1999 (1999-06-02) column 5, line 11 - line 38 column 6, line 6 - line 21; figures 1,2	1,2 3,4,6
X	US 6 050 955 A (MATULA PAUL A ET AL) 18 April 2000 (2000-04-18) column 6, line 16 - line 46; figures 2-4	1
Y A	US 5 944 673 A (PRIVITERA SALVATORE ET AL) 31 August 1999 (1999-08-31) column 6, line 66 -column 7, line 23; figure 2	3,4,6 5
A	WO 97 24070 A (JANSSENS JACQUES PHILLIBERT) 10 July 1997 (1997-07-10) page 4, line 28 -page 5, line 9; figure 1	1-4

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 May 2002	05/06/2002

Name and mailing address of the ISA	Authorized officer
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Information on patent family members

International Application No
PCT/US 02/02987

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 0919192	A	02-06-1999	AU	9326698 A	10-06-1999
			EP	0919192 A2	02-06-1999
			JP	11235346 A	31-08-1999
US 6050955	A	18-04-2000	US	2002029007 A1	07-03-2002
US 5944673	A	31-08-1999	NONE		
WO 9724070	A	10-07-1997	BE	1009902 A3	07-10-1997
			AU	1361997 A	28-07-1997
			WO	9724070 A1	10-07-1997
			EP	0959774 A1	01-12-1999
			JP	2000502576 T	07-03-2000

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